DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

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Philadelphia, PA 19106

Telephone: 215-597-4390

01-PHI-18

WARNING LETTER

May 7, 2001

FEDERAL EXPRESS

Richard Garman
President/CEO
Wayne Memorial Hospital
601 Park Street
Honesdale, PA 18405

Re: Inspection ID: 2076050006

Dear Mr. Garman:

We are writing to you because on April 24, 2001, your mammography facility was inspected by a representative from the Commonwealth of Pennsylvania, acting in behalf of the Food and Drug Administration (FDA). Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

This inspection revealed the following level 1 and level 2 noncompliances:

Level 1 Inspection Finding:

Quality Standards – Equipment: Daily Quality Control Tests **[21 CFR 900.12(e)(1)]**
- Use of Test Results **[21 CFR 900.12(e)(8)(ii)(A)]**

".....A processor performance test shall be performed on each day that clinical films are processed for that day...(ii) The mid-density shall be within +/- 0.15 of the established operating level....(iii) The density difference shall be within +/- 0.15 of the established operating level."

"If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:.... Before any further examinations are performed or any films are processed using a component of the mammography system that failed.....".

OBSERVATION: Mammograms were processed in the [redacted] when it was out of limits on at least 5 days.

Patient exams were performed when the processor was operating out limits for mid-density on 10/5,6,9,10.11,12,13/2000, 3/30/2001, and 4/2,3,4,5,6/2001.

Patient exams were performed when the processor was operating out of limits for mid-density on 11/15,16,17,20,21,22,24,27,28,29,30/2000, 12/1,4,5,6,7/2000, 1/15,16,17, 23/2001, and 2/1/2001.

Level 2 Inspection Findings:

Quality Standards – Equipment: Daily Quality Control Tests **[21 CFR 900.12(e)(1)]**
- Use of Test Results - **[21 CFR 900.12(e)(8)(ii)(A)]**

".....A processor performance test shall be performed on each day that clinical films are processed for that day...(ii) The mid-density shall be within +/- 0.15 of the established operating level....(iii) The density difference shall be within +/- 0.15 of the established operating level."

"If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken....."

OBSERVATION: Corrective actions for processor QC failures were not documented at least once.

Corrective action was not taken in response to the processor QC failures as described in the comments for the level 1 finding above.

OBSERVATION: Processor QC records in the month of 12/2000 were missing for at least [redacted] but less than [redacted] of operating days.

Processor QC was not performed on 12/14,28/2000, yet patient exams were processed both days.

Quality Standards – Equipment: Weekly Quality Control Tests **[21 CFR 900.12(e)(2)]**
- Use of Test Results - **[21 CFR 900.12(e)(8)(ii)(A)]**

"Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly. (i)....(ii) The optical density of the film at the center of the phantom image shall not change by more than +/- 0.20 from the established operating limit....".

"If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:.... Before any further examinations are performed or any films are processed using a component of the mammography system that failed....."

OBSERVATION: Corrective action before further exams, for a failing image score, or a phantom background optical density or density outside the allowable regulatory limits was not documented for the [redacted] mammography unit.

Review of the phantom QC records for the [redacted] mammography unit found that the background density difference exceeded the established operating limit by more than +/- 0.20 on 11/27,30/2000, 12/28/2000, and 1/10/2001.Patient exams were performed during the weeks of these phantom images. Corrective action was not taken before further exams in each of the above failed test results.

Quality Standards – Equipment: Weekly Quality Control Tests **[21 CFR 900.12(e)(2)(i)]**

"Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly... The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition."

OBSERVATION: The phantom QC is not adequate because the image was not taken at the clinical setting for the [redacted] mammography unit.

The clinical setting for the typical patient used by your facility is the [redacted] at [redacted] density. Your facility used a [redacted]" density setting for the phantom image on 12/7/2000 and 1/17/200. There was no documentation showing that the patient exams were also performed at [redacted] density setting. The phantom image QC test must be performed with the same density setting used for the typical patient.

The specific problems noted above appear on the attached MQSA Facility Inspection Report issued to the facility on April 24, 2001. The inspection also found that your facility did not perform the crossover procedure for the processor correctly resulting in incorrect operating limits for mid-density and density difference. Also, the wording of the assessment category for the category 2 and 5 exams was not correct. Your infection control procedure did not include the requirement to have logs or charts indicating that the infection control procedures were performed when the mammography equipment came into contact with blood or other potentially infectious materials.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to:

- placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring,
- assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with the Standards,
- suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

Please note that FDA regulations do not preclude a State from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action, therefore, you should consider the more stringent State requirements, if any.

It is necessary for you to act on this matter immediately. Please address the following items in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- provide a copy of your written procedure for performing the processor QC test which includes the criteria for acceptable processor operation and the requirement to perform processor QC each day of operation, to take and document corrective action before patient exams are processed; also steps to

follow for performing the crossover procedure and establishment of operating limits for mid-density and density difference;

- provide a copy of your processor QC chart which shows the correct operating limits for MD and DD and the data showing how these operating limits were established;
- provide a copy of your written procedure for performing the phantom QC test which includes a statement of what technique to use for the test and the criteria for a passing phantom image and procedures for taking and documenting corrective action when the phantom QC test fails for any of the required parameters.
- provide a copy of your written procedure for tracking positive mammograms and obtaining biopsy results for all positive exams including those biopsies not performed at Wayne Memorial Hospital
- provide a copy of your revised written infection control procedure which includes the requirement to log or chart when infection control procedures were performed when the mammography equipment came into contact with blood or other potentially infectious materials.
- provide a copy of your procedure for assigning assessment categories to each medical report and the wording to be used for each category, including the revised wording for the category 2 and 5 exams.
- provide documentation showing the Quality Control Technologist is aware of their responsibility to oversee the QC program and verifies that QC tests are performed correctly, that corrective action is taken when test results fail, and that other individuals performing any of the required QC tasks are properly trained.

Please submit your response to:

Robert E. Davis
Mammography Specialist
U.S. Food & Drug Administration
7 Parkway Center, Rm 390
Pittsburgh, PA 15220

With a copy to:

Joseph Pryber
PA Dept. of Environmental Protection
Bureau of Radiation Protection
Lee Park, Suite 6010
555 North Lane
Conshohocken, PA 19428

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography. If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Robert E. Davis at 412-644-3394.

Sincerely,

Cynthia J. Lakestraw

for Thomas Gardine
District Director
Philadelphia District

Attachment: MQSA Facility Inspection Report ID: 1459530009

cc: Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191

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PA Dept. of Environmental Protection
Bureau of Radiation Protection
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